

### REMARKS

The pending Office Action addresses claims 21-36, rejecting all the claims. No amendments are submitted in this response. In view of the remarks below, Applicants respectfully request reconsideration of the application.

#### *Double Patenting Rejections*

The Examiner rejects claims 21-36 under an obviousness-type double patenting rejection as being unpatentable over claims 1-41 of U.S. Patent No. 6,325,769. The Examiner also rejects claims 21-36 under an obviousness-type double patenting rejection as being unpatentable over claims 1-18 of U.S. Patent No. 6,113,559. Applicant will file a timely terminal disclaimer to overcome these rejections, once the Examiner indicates that claims 21-36 are allowable.

#### *Prior Art Rejections*

The present invention concerns the use of particular forms of *ultrasound* to improve skin appearance (e.g., reduce wrinkles). Independent method claim 21 recites a method for improving skin appearance by introducing ultrasound energy into a dermis layer of skin *at sufficiently high pressure amplitudes to propagate the ultrasound energy non-linearly* to induce new connective tissue formation. Likewise, independent apparatus claim 33 requires an ultrasound transducer and a control device constructed and arranged to control an ultrasound transducer and induce ultrasound energy at sufficiently high pressure amplitudes so as to cause non-linear propagation of the energy into the dermis layer sufficient to induce new connective tissue formation. None of these limitations are found in the cited references.

There is only one substantive issue remaining in this case. Claims 21-36 stand rejected under 35 U.S.C. §103(a) as being obvious over Eckhouse '631 (U.S. Patent No. 5,626,631) in view of Cocks et al. (U.S. Patent No. 4,825,851).

Briefly, the Examiner's rejection relies on a prior art disclosure of a *laser (or light based)* skin therapy device and the purported *interchangeability* of laser and ultrasound devices in producing shock waves (or non-linear propagation of ultrasound energy). For each of the following reasons, Applicant respectfully disagrees and requests withdrawal of this prior art rejection.

Eckhouse teaches treatments for skin disorders, such as pigmented lesions, by the application of *radiant* energy from a *light source* to coagulate blood within the skin. Specific *light* sources and *optical* waveguides are disclosed. The Office Action acknowledges that "*Eckhouse '631 does not teach the use of ultrasound for shock-wave generation or alternatively stated the non-linear propagation of ultrasound through the dermis layer.*"

The Office Action argues that "*Eckhouse teaches a light source to create shock waves in a way much like the pulsed lasers...*" and cites column 2, line 66 through column 3, line 12.

Applicant disagrees. This passage from the Eckhouse patent is reproduced below:

In addition to being used for treating skin disorders, lasers have been used for invasive medical procedures such as lithotripsy and removal of blood vessel blockage. In such invasive procedures laser light is coupled to optical fibers and delivered through the fiber to the treatment area. In lithotripsy the fiber delivers light from a pulsed laser to a kidney or gallstone and the light interaction with the stone creates a shock wave which pulverizes the stone. To remove blood vessel blockage the light is coupled to the blockage by the fiber and disintegrates the blockage. In either case the shortcomings of lasers discussed above with respect to laser skin treatment are present. Accordingly, a treatment device for lithotripsy and blockage removal utilizing a flashlamp would be desirable.

There is no suggestion in the cited passage that the radiant energy from lasers or flashlamps operates in any manner akin to ultrasound. A fair reading of this passage from the Eckhouse '631 patent would merely suggest that *laser light* can interact with (e.g., heat) kidney stones and create shock waves that pulverize the *kidney stone* – and a device that utilized a *flashlamp* rather than a laser would be desirable. There is no mention of ultrasound, much less *non-linear propagation of ultrasound energy into the dermis layer*, as recited in Applicant's principal claims.

The Cocks et al. reference does not remedy these deficiencies. Contrary to the assertion on page 4 of the Office Action that "*Cocks et al. teaches the interchangeability of ultrasound with laser to create shock waves (see col. 1, lines 30-32),*" Cocks et al. actually teach the opposite. Again, the passage cited by the Examiner from the Cocks et al. patent background is reproduced below:

Presently, several non-invasive sonic methods and invasive ultrasonic and laser fragmentation methods to destroy kidney stones are being explored.

There is no suggestion that ultrasound and laser energy are interchangeable. In fact, the word “*laser*” is never mentioned again in the Cock et al. patent. The primary teaching of Cocks et al. concerns the infusion of solutions into the kidney to lower the fracture strength of kidney stones during ultrasound lithotripsy. Cocks et al. is not even analogous art since it relates to kidney stone destruction not improving skin appearance.

Finally, Applicant disagrees with the Examiner’s suggestion that Applicant has acknowledged the exchangeability of ultrasound with lasers by his own admission. Presumably, the passage relied upon by the Examiner is found in the last paragraph of the specification:

Having thus described at least one illustrative embodiment of the invention, various alterations, modifications, and improvements will readily occur to those skilled in the art. For example, various alternative acoustic pulse or “shock-wave” generators can be employed in lieu of the above described ultrasound transducers. Such alternative energy generators include piezoelectric, electric spark and laser-triggered pulse forming devices operating on rapid state changes of liquid media or on thermoelastic expansion.

It should be clear that this passage is concerned with alternative *acoustic* pulse generators, including laser-triggered devices. It does not suggest the interchangeability of ultrasound (acoustic) energy with radiant (light) energy. If the Examiner would like further evidence that ultrasound and radiant energy are not interchangeable, Applicant would be happy to submit an expanded explanation via a Rule 132 Declaration.

Most fundamentally, neither of the cited references fairly teaches or suggests the invention as claimed. There is no suggestion in either reference of the advantages of applying *non-linear ultrasound energy at high pressure amplitudes* to the *dermis layer* in order to change the *smoothness of the epidermis*.

Because the cited references fail to disclose the propagation of *ultrasound energy* in a *non-linear fashion* to induce *new connective tissue formation* in the *dermis layer* of skin, as required of the claims, the references cannot be said to render the invention obvious. Accordingly, withdrawal of the single remaining basis for rejection is earnestly requested.

A request for a three month extension of time up to and including August 9, 2005, to reply to the outstanding Office Action and a check for the extension fee are submitted herewith.

### Conclusion

In view of the above, each of the presently pending claims in this application is now believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. If further evidence by declaration is desired, the Examiner is urged to call the undersigned at the number indicated below. Likewise, if the only remaining issue is the need for Terminal Disclaimers, please call so that the filing of such disclaimers can be expedited.

Dated: August 9, 2005

Respectfully submitted,

By 

Thomas J. Engellemer

Registration No.: 28,711

NUTTER MCCLENNEN & FISH LLP

World Trade Center West

155 Seaport Boulevard

Boston, Massachusetts 02210-2604

Tel. (617) 439-2734

Fax (617) 310-9734

Attorneys/Agents for Applicant